REMARKS

Claims 26, 28-31, and 33-35 are presently pending in the case. Claims 27 and 32 have been cancelled without prejudice or disclaimer. Claims 26, 28, 31, 33, and 34 have been amended. The claim amendments are supported by the specification and claims as originally filed.

Claim rejections under judicially created doctrine of Double Patenting

The Examiner rejected claims 26-35 under the judicially created doctrine of double patenting as being unpatentable over the claims of U.S. Patent 6,685,967. Upon the indication of allowable subject matter, Applicant will submit a terminal disclaimer in accordance with the Examiner's suggestion.

Claim rejections under 35 USC 102(b) and under 35 USC 103(a)

The Examiner rejected claims 26-29 and 31-34 under 35 USC 102(b) as being anticipated by U.S. Patent 5,354,562 to Platz et al (hereinafter Platz et al) and as being unpatentable under 35 USC 103(a) over Platz et al. The rejections are traversed.

Platz et al does not anticipate claims 26-29 and 31-34. To sustain a section 102 rejection, the reference relied upon, must disclose each and every element of the claimed invention. Non-disclosure of a single element of the claim negates anticipation. Claims 26 and 31, for example, are to a stable, dry powder insulin composition produced by a method comprising dissolving insulin in an aqueous buffer at to form a solution, adding a pharmaceutical carrier to the solution; and spray drying the solution to produce substantially amorphous particles, wherein insulin is present in the particles at from 15% to 80% by weight. It is respectfully submitted that these positively recited features are absent in the teachings of Platz et al, thereby precluding a section 102 rejection because each and every element of the claim is not taught by the cited reference. Thus, the Examiner is respectfully requested to reconsider the language of claim 26 and withdraw the rejection thereunder.

Platz et al does not disclose or suggest a composition as presently claimed. Instead, Platz et al teaches that it is desirable to produce compositions where a polypeptide is present at less than 10% of the total solids. The examples of Platz et al show polypeptide drug at from 0.07% to 8.26% by weight of the total solids in a solution to be lyophilized. The low percentage is found in Example 2, Solution B (column 5 lines 25-68) and the high percentage is found in Example 3 (column 3 lines 1-24). Since Platz et al does not disclose the weight percent of insulin as recited in claim 34, it does not disclose all features positively set forth in claim 34.

In particular, column 4 lines 20-30 of Platz et al, does not teach a composition that is from 15% to 80% insulin. Specifically, Platz et al recites:

> "By using the improved process of the invention, insoluble contaminants in the powder product are reduced to below about 5% by weight, more usually below about 2% by weight. These contaminants have been found to increase degradation of the active ingredient in the milled powder product. In the case of polypeptides that are otherwise degraded by jet milling, the invention reduces the extent of degradation such that the polypeptide drug component of the milled powder constitutes at least about 85% active drug, preferably at least about 95% active drug." (emphasis added)

This recitation speaks only to the "drug component of the milled powder". The invention of Platz et al and the discussion within Platz et al is to the reduction of degradation of the active drug so that at least about 85% of the drug component remains active. This recitation is not directed to the percentage of active drug within the entire powder, but rather the percentage of drug within the drug component of the powder that remains active during the formulation process. Thus, the "drug component" of the composition of Platz et al may be from 85% to 100% active agent, but the powder may have other components, as discussed throughout the teachings of the reference and as described above.

Since Platz et al does not disclose, teach or suggest the invention as set forth in claims 26 and 31, Platz et al does not anticipate or render obvious the invention. Applicant requests withdrawal of the rejections of claims 26 and 31 and the claims depending therefrom.

The Examiner rejected claims 30 and 35 under 35 USC 103(a) as being unpatentable over U.S. Patent 5,354,562 to Platz et al in view of U.S. Patent 5,042,975 to Chien (hereinafter Chien). The rejection is traversed.

Claims 30 and 35 depend from claims 26 and 31, respectively. Claims 26 and 31 are not rendered unpatentable by Platz et al, as discussed above. Chien does not make up for the deficiencies of Platz et al. Thus, claims 30 and 35 are not rendered unpatentable by Platz et al and Chien. Applicant requests withdrawal of the rejections.

Information Disclosure Statement

Applicant is under separate cover an information disclosure statement in compliance with MPEP section 609. Indication of consideration of the references provided is requested.

Conclusion

The Examiner is respectfully requested to consider the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

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Dated: 10 JUN 2005

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